Focused Cardiac Ultrasound to Guide the Diagnosis of Heart Failure in Pregnant Women in India

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Background: Cardiac complications are a leading cause of maternal death. Cardiac imaging with echocardiography is important for prompt diagnosis, but it is not available in many low-resource settings. The aim of this study was to determine whether focused cardiac ultrasound performed by trained obstetricians and interpreted remotely by experts can identify cardiac abnormalities in pregnant women in low-resource settings.

Methods: A cross-sectional study was conducted among 301 pregnant and postpartum women recruited from 10 hospitals across three states in India. Twenty-two obstetricians were trained in image acquisition using a portable cardiac ultrasound device following a simplified protocol adapted from focus-assessed transthoracic echocardiography protocol. It included parasternal long-axis, parasternal short-axis, and apical four-chamber views on two-dimensional and color Doppler. Independent image interpretation was performed remotely by two experts, in the United Kingdom and India, using a standard semiquantitative assessment protocol. Inter-rater agreement between the experts was examined using Cohen's κ. Diagnostic accuracy of the method was examined in a subsample for whom both focused and conventional scans were available.

Results: Cardiac abnormalities identified using the focused method included valvular abnormalities (27%), rheumatic heart disease (6.6%), derangements in left ventricular size (4.7%) and function (22%), atrial dilatation (19.5%), and pericardial effusion (30%). There was substantial agreement on the cardiac parameters between the two experts, ranging from 93.6% (κ = 0.84) for left ventricular ejection fraction to 100% (κ = 1) for valvular disease. Image quality was graded as good in 79% of parasternal long-axis, 77% of parasternal short-axis and 64% of apical four-chamber views. The chance-corrected κ coefficients indicated fair to moderate agreement (κ = 0.28-0.51) for the image quality parameters. There was good agreement on diagnosis between the focused method and standard echocardiography (78% agreement), compared in 36 participants.

Conclusions: The focused method accurately identified cardiac abnormalities in pregnant women and could be used for screening cardiac problems in obstetric settings. (J Am Soc Echocardiogr 2022;■:■-■.)

Keywords: Focused cardiac ultrasound, FoCUS, Obstetrics, Cardiac abnormalities, Low-resource settings

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Abbreviations

2D = Two-dimensional

DICOM = Digital Imaging and Communications in Medicine

FoCUS = Focused cardiac ultrasound

LMIC = Low- and middle-income country

LVEF = Left ventricular ejection fraction

MaatHRI = Maternal and Perinatal Health Research Collaboration, India

PLAX = Parasternal long-axis

PSAX = Parasternal short-axis

Cardiac complications are a leading cause of indirect maternal deaths in the United Kingdom,[1] Europe,[2] and the United States,[3] and they are also an important cause of maternal morbidity and mortality in low- and middle-income countries (LMICs).[1] In India, we estimated the incidence of heart failure in pregnant and postpartum women to be about 2 per 1,000 hospital births, with a case fatality rate of 40%. Prompt echocardiographic investigation is essential for diagnosing maternal cardiac complications for timely management to prevent death. However, many hospitals in low-resource settings have neither the facilities nor a cardiologist, or the investigation is not quick enough to save the lives of seriously ill patients. According to the Cardiological Society of India, there is one cardiologist per 30,000 population, with the distribution skewed in favor of the more developed parts of the country and urban areas.[4] Focused cardiac ultrasound (FoCUS) could be a low-cost solution for prompt diagnosis of cardiac complications in pregnant women in an obstetric unit in low-resource settings. Obstetricians can be trained to acquire images, which can be interpreted remotely by experts.

The concept of FoCUS[5] is widely recommended for settings where standard echocardiography is not readily available or to augment clinical assessments for time-sensitive clinical decisions.[6-9] It is based on the concept of "task shifting," whereby trained health care providers (with no previous expertise) perform echocardiography with portable devices using a simple imaging protocol.[6,7,10] This method has been proved to improve efficiency in initial clinical diagnosis, which can be later confirmed on standard transthoracic echocardiography.[6,7,10] Although at present, FoCUS is used mainly in high-income settings in emergency medicine, anesthesia, and critical care, we found some studies from LMICs showing that this approach was effective in screening and early diagnosis of rheumatic heart disease in schoolchildren,[11-16] even when images were acquired by nonexperts and interpreted remotely by experts.[17] However, there is no evidence to support the diagnostic accuracy of FoCUS images of pregnant women acquired by trained obstetricians and interpreted remotely by experts. The objectives of our study were to (1) determine whether FoCUS performed by trained obstetricians and interpreted remotely by experts can identify cardiac abnormalities in pregnant and postpartum women in low-resource settings in India and (2) examine agreement between two experts independently reading the images remotely to assess reliability of the interpretation protocols developed for the focused approach.

METHODS

Study Design and Population

This was a cross-sectional study nested within an ongoing case-control study examining the clinical characteristics, risk factors, and outcomes of acute heart failure syndrome in pregnant and postpartum women in India undertaken through the Maternal and Perinatal Health Research Collaboration, India (MaatHRI) platform[18] at 10 hospitals across three states. Portable ultrasound devices are used to scan the hearts of pregnant and postpartum women with suspected heart failure and control participants (no symptoms of heart failure) by trained obstetricians using a simple image acquisition protocol. The images are interpreted remotely by experts following a standard image interpretation protocol. Our methodology is based on the FoCUS method, defined as "a goal directed, simplified, qualitative examination, mainly based on recognition of dichotomic gross abnormalities (presence/absence) and performed by the physician in charge of the patient."[10]

The study included images from participants recruited between February 2019 and July 2021. Inclusion criteria for suspected heart failure cases were (1) a pregnant or postpartum woman (≤12 months after childbirth) presenting with breathlessness (≥15 breaths/min) with or without one or more of the following clinical signs: elevated jugular venous pressure, cardiac murmur or gallop rhythm or signs of pulmonary edema (crackles in the lung or pink frothy sputum); (2) age ≥ 18 years; and (3) woman or "next of kin" willing to give informed consent to participate in the study. Control subjects were (1) women ≥18 years of age (2) who were not diagnosed with heart failure and (3) who had given birth within 2 days of the case presenting at the hospital. Women were excluded if they were <18 years of age, or if they were unwilling to provide informed consent. Participants were recruited from inpatient units, and consent was obtained by a research nurse. The study was approved by ethics committees in India and the University of Oxford.

Independent image interpretation data from two echocardiography experts, one from Oxford, United Kingdom, and another from Assam, India, were available for a subset of these participants. For a further subset of participants with heart failure, data from a standard comprehensive echocardiographic scan performed using a GE Logiq P9 (GE Healthcare) ultrasound machine were available. The standard scan was performed by a clinical echocardiography specialist as part of clinical care, and focused cardiac imaging was completed by a trained obstetrician in the hospital.

Training of Obstetricians

Twenty-two obstetricians from 10 hospitals in India were provided hands-on training in image acquisition using portable echocardiography devices (Lumify; Philips Healthcare) in November 2018. The portable unit consists of a handheld probe connected to an Android tablet (Samsung) in which the imaging software is installed. The training comprised 2 days of face-to-face intensive echocardiographic image acquisition sessions with a lecture, followed by multiple rounds of supervised hands-on practice in echocardiographic imaging using the portable devices on volunteers first and then on pregnant women. In our study hospitals as well as in most hospitals in India, obstetric ultrasound scans are performed by obstetricians. A few obstetricians with insufficient prior experience of ultrasound imaging were provided with additional personalized training. The image acquisition skills were assessed for each obstetrician until they were able to scan independently. The training structure, materials, and assessment were designed and conducted by two echocardiography specialists from the Oxford Cardiovascular Clinical Research Facility at the University of Oxford.

After the hands-on training in India, each obstetrician uploaded scans from at least 10 pregnant women for remote assessment

HIGHLIGHTS

- FoCUS can be used in low-resource obstetric settings.
- Trained obstetricians acquired high-quality images with portable cardiac ultrasound.
- Images were interpreted remotely by experts using an image interpretation protocol.
- Most of the views (64%-79%) were graded as good quality by experts.
- Agreement was 78% on diagnosis between focused and standard echocardiography.

conducted at the Cardiovascular Clinical Research Facility before the start of participant recruitment. Remote supervision and constructive feedback on image quality were regularly provided to all obstetricians. Two remote refresher training sessions were organized through video conferencing in September 2019 and March 2020.

FoCUS Image Acquisition and Optimization

Cardiac image acquisition was performed by the trained obstetricians following a simplified protocol adapted from the focus-assessed transthoracic echocardiography protocol.[19] Our imaging protocol included the recommended views for FoCUS,[5,6,10] the parasternal long-axis (PLAX) view, the parasternal short-axis (PSAX) view at the papillary muscle level, and the apical four-chamber view, but the subcostal view was not included, as it was difficult to obtain in pregnant women because of the gravid uterus. Color flow Doppler was applied to the mitral and aortic valves in the PLAX view and to the mitral and tricuspid valves in the apical four-chamber view, as illustrated in the MaatHRI focused image acquisition protocol (Figure 1). Image optimization was enhanced by adjusting the gain and depth settings for two-dimensional (2D) imaging, and the color box size and position to assess valvular flow.

The protocol met the objectives of FoCUS and allowed us to examine the specific targets[5,6,10]: pericardial effusion, ventricular and atrial enlargements, ventricular dysfunction, valvular abnormalities, and presence of thrombus. We were also able to categorize valvular abnormalities into nonsignificant (mild) and significant (moderate to severe). However, we were unable to examine pathologies of the inferior vena cava, as the subcostal view was not possible.

Image Transfer and Interpretation

Anonymized cardiac scans were transferred as Digital Imaging and Communications in Medicine (DICOM) files to a server at the University of Oxford. The data transferred from the Android tablets was encrypted in transit using a bespoke Android application on the tablets. The images were accessed by the two echocardiography specialists using authenticated login ID and password. They were analyzed using a DICOM viewer, OsiriX MD (https://www.osirix-viewer.com) and reported using an electronic standard online form with questions related to specific cardiac and image quality parameters answered using either dichotomized (e.g., present or absent) or ordered categorical options (e.g., none, mild, moderate, or severe). A copy of the form is included in the Supplemental Appendix. Blinded independent reporting by the experts was conducted to assess interobserver variability. This allowed us to assess whether the semiquantitative protocol could be reliably applied to replicate the findings from the focused cardiac images for diagnosing pathologies and image quality.

A standard interpretation protocol on the basis of semiquantitative assessment following the latest guidelines[20-22] and comparable with the FoCUS image interpretation protocol developed by Casella *et al.*[10] was used by the two experts to evaluate valvular abnormalities, structural and functional abnormalities for the left and right ventricles, enlargement of the left and right atria, and the presence of pericardial effusion and/or thrombus. Valvular assessment for the aortic, mitral, and tricuspid valves was performed using prespecified categories for levels of severity for valvular regurgitation and valvular stenosis (none or absent, mild or nonsignificant, and moderate to severe or significant). Severity was determined on the basis of the valve morphology, mobility, and color flow according to the qualitative assessment guidelines for valvular regurgitation[23] and stenosis[24,25] and classified as nonsignificant or significant, as described in Table 1. Valves with morphologic features of rheumatic heart disease, such as thickened leaflets with restricted motion, were identified, and affected valves were reported. Left ventricular size was assessed by measuring the largest dimension of the left ventricular cavity perpendicular to the interventricular septum and the inferolateral wall. A selection of one of the ranges (3.9-5.3, 5.4-5.7, 5.8-6.1, or >6.1 cm) was made following the measurement.

The left ventricular ejection fraction (LVEF) was estimated visually by evaluating the difference between the largest (diastole) left ventricular cavity and the smallest (systole) from the three 2D views and categorized as >70%, 55% to 69%, 45% to 54%, 30% to 44%, or <30%. Right ventricular size was assessed from the apical four-chamber view by measuring the widest basal dimension before the tricuspid valve closure; a diameter of >4.2 cm was considered to indicate an enlarged right ventricle. The presence of ventricular regional wall motion abnormalities was also reported, along with identifying the abnormal segments. Left atrial enlargement was estimated by measuring its largest dimension in the PLAX view (enlarged when >3.8 cm). From the apical four-chamber view, left and right atrial areas were measured, and cutoff values of >20 and >18 cm^2 were used for left and right atrial enlargement, respectively.[20,21] The presence of pericardial effusion was reported with visual estimation of the size (small or large), location (global or localized), and the presence of fibrin strands. Finally, the presence of thrombus was reported with its location, attachment, and mobility.

Image Quality Assessment

Image quality was evaluated regularly to maintain consistent standard and quality across all hospitals, with regular feedback provided to the obstetricians. The assessment was conducted independently by the two experts following a standard protocol. Each image was graded as good, medium, or poor on the basis of the structural visualization and image optimization according to the criteria shown in Figure 2. Color flow Doppler box size and position were also evaluated.

Statistical Analysis

Descriptive analysis was conducted to summarize the echocardiographic findings (cardiac parameters) and the quality of the scans for all participants. Results are reported as frequency and percentage for each cardiac and quality parameter. In the subsample of participants for whom image interpretation data from both experts were

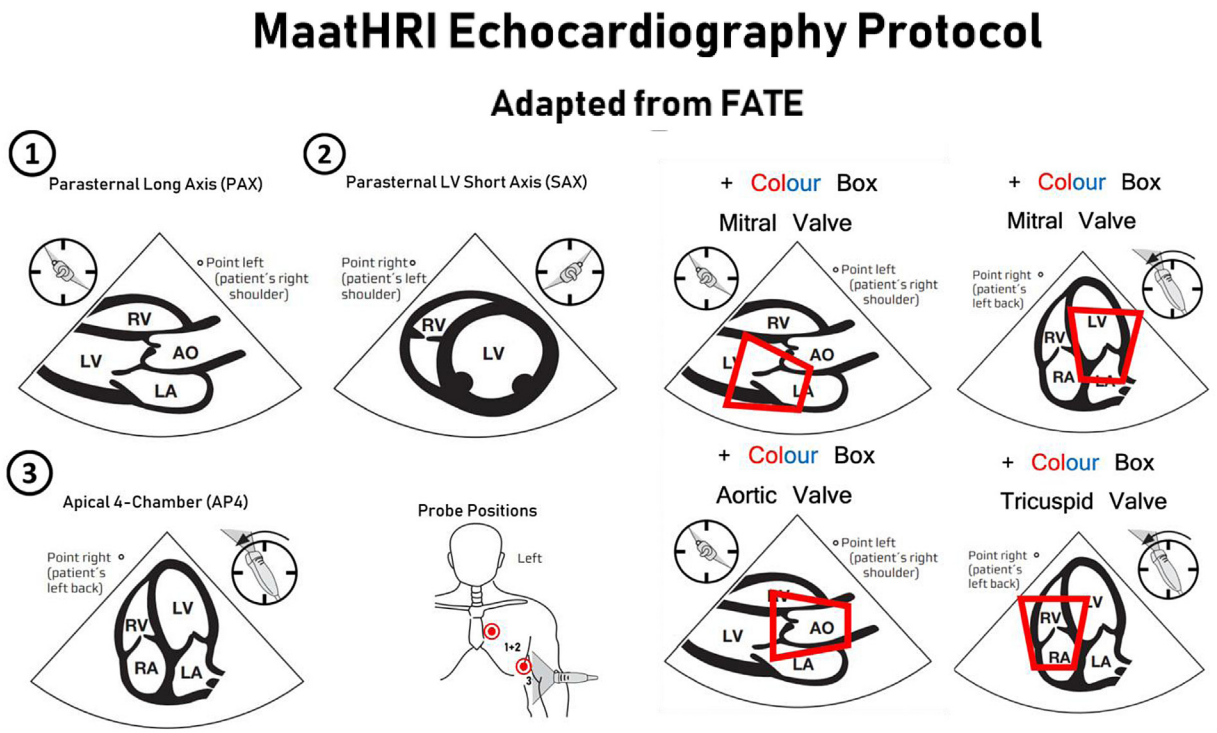

Figure 1 MaatHRI focused echocardiographic image acquisition protocol. *AO*, Aorta; *FATE* , focus-assessed transthoracic echocardiography; *LA*, left atrium; *LV*, left ventricle; *RA*, right atrium; *RV*, right ventricle.

available, we examined chance-corrected interrater agreement using Cohen's κ coefficient. For each parameter, percentage agreement, κ statistic with 95% CI, and *P* value were reported. We also conducted additional analysis to examine the diagnostic accuracy of the focused method in the subsample of cases for which both focused and standard scans were available by calculating the percentage agreement on cardiac complications identified between the two scans, taking into account the time difference between the two types of scans. All statistical analyses were performed using Stata version 16.1 SE (StataCorp).

RESULTS

A total of 301 pregnant and postpartum women recruited between February 2019 and July 2021 (Figure 3) who underwent FoCUS imaging by the trained obstetricians were included in the study. Of these, 172 were suspected to have heart failure and 129 were control participants. The recruitment rate was 100%, as all eligible women provided informed consent to participate in the study. For 29 women who were too unwell to provide consent, informed consent was obtained from next of kin. Cardiac parameters from all 301 women were included in the analysis. However, five women with suspected heart failure left the hospital against medical advice after their cardiac scans, and thus their clinical data and blood samples could not be collected. Two of the five women had rheumatic valve disease, one had a high LVEF (>70%) but no other echocardiographic abnormality, another had significant tricuspid regurgitation, and one woman had both left and right atrial enlargement. Sociodemographic characteristics and pregnancy and medical histories of all 301 participants and clinical characteristics of the 172 women presenting with suspected heart failure are presented in Table 2. A total of 116 women were pregnant, and 180 were postpartum at the point of recruitment, but the pregnancy status of the five women with no clinical data is not known. Image interpretation data from the two experts were available for 109 participants, and 36 participants with suspected heart failure underwent standard echocardiography in addition to the focused scan.

A wide range of cardiac abnormalities were identified in the study population using the focused approach (Table 3). Overall, mitral valve disease was the most common valvular abnormality found in the study population (81 women [28%]). A total of 64 women (22%) had mitral regurgitation, and 40% of these were significant (moderate to severe). Nine of the 64 women were from the control group: eight had nonsignificant (mild) and one had significant regurgitation. Mitral stenosis was present in 17 women (6%), and all of these were graded as significant. Although 59 women (22%) were found to have tricuspid regurgitation, including 16 control participants, a majority were classified as nonsignificant. Two women had tricuspid stenosis, and one woman had significant aortic valve stenosis. Aortic valve regurgitation was found in 15 participants, and the majority (12 of 15) were nonsignificant. Rheumatic heart disease was reported in 20 participants (6.6%), and all of them had mitral valve involvement, with aortic and tricuspid valve involvement found in 1% and 1.3%, respectively. Figure 4 presents the apical four-chamber view of a case with rheumatic heart disease and significant mitral stenosis captured using the focused method.

Left ventricular enlargement was found in 14 participants (4.7%), and 65 participants (22%) had reduced LVEFs, including five women from the control group. Enlargement of the right ventricle was reported in 19 participants (6.7%), including one control participant. The left atrium was dilated in 57 participants (19.5%), including two control subjects, and 28 (10%) had right atrial

Table 1 Qualitative assessment criteria for valvular stenosis and regurgitation

Valvular abnormality	Assessment criteria
Mitral valve stenosis • PLAX view • Apical four-chamber view	Significant (moderate to severe): abnormal valve morphology and mobility (thickened/fused leaflets/restricted mobility) with the presence of large turbulent mitral flow during diastole with or without left atrial enlargement Nonsignificant (mild): normal or abnormal valve morphology and mobility with the presence of a small turbulent mitral flow during diastole, and normal left atrial size Absent (none): normal valve morphology and mobility with no turbulent flow seen at the mitral valve in color flow Doppler
Mitral valve regurgitation • PLAX view • Apical four-chamber view	Significant (moderate to severe): abnormal valve morphology and mobility (thickened/obvious coaptation defect/flail or restricted mobility) with the presence of a large central or eccentric regurgitation jet with or without left atrial and/or ventricular enlargement Nonsignificant (mild): normal or abnormal valve morphology and mobility with the presence of a small central regurgitation jet, and normal left atrial and ventricular size Absent (none): normal valve morphology and mobility with no regurgitation jet seen in color flow Doppler
Aortic valve stenosis • PLAX view	Significant (moderate to severe): abnormal valve morphology and mobility (thickened/fused leaflets/restricted mobility) with the presence of large turbulent aortic flow during systole with or without increased left ventricular wall thickness Nonsignificant (mild): normal or abnormal valve morphology and mobility with the presence of a small turbulent aortic flow during systole, and normal left ventricular wall thickness Absent (none): normal valve morphology and mobility with no turbulent flow seen at the aortic valve in color flow Doppler
Aortic valve regurgitation • PLAX view	Significant (moderate to severe): abnormal valve morphology and mobility (thickened/obvious coaptation defect/flail or restricted mobility) with the presence of a large central or eccentric regurgitation jet with or without aortic root and/or left ventricular enlargement Nonsignificant (mild): normal or abnormal valve morphology and mobility with the presence of a small central regurgitation jet, and normal aortic root and left ventricular size Absent (none): normal valve morphology and mobility with no regurgitation jet seen in color flow Doppler
Tricuspid valve stenosis • PLAX view • Apical four-chamber view	Significant (moderate to severe): abnormal valve morphology and mobility (thickened/fused leaflets/restricted mobility) with the presence of large turbulent tricuspid flow during diastole with or without right atrial enlargement Nonsignificant (mild): normal or abnormal valve morphology and mobility with the presence of a small turbulent tricuspid flow during diastole, and normal right atrial size Absent (none): normal valve morphology and mobility with no turbulent flow seen at the tricuspid valve in color flow Doppler.
Tricuspid valve regurgitation • PLAX view • Apical four-chamber view	Significant (moderate to severe): abnormal valve morphology and mobility (thickened/obvious coaptation defect/flail or restricted mobility) with the presence of a large central or eccentric regurgitation jet with or without right atrial and/or ventricular enlargement Nonsignificant (mild): normal or abnormal valve morphology and mobility with the presence of a small central regurgitation jet, and normal right atrial and ventricular size Absent (none): normal valve morphology and mobility with no regurgitation jet seen in color flow Doppler

Large and small jets were judged on the basis of the jet size relative to the corresponding chamber size (e.g., the size of mitral regurgitation jet relative to left atrial size). The criteria used for chamber enlargement assessment are described in details in the "Methods" section.

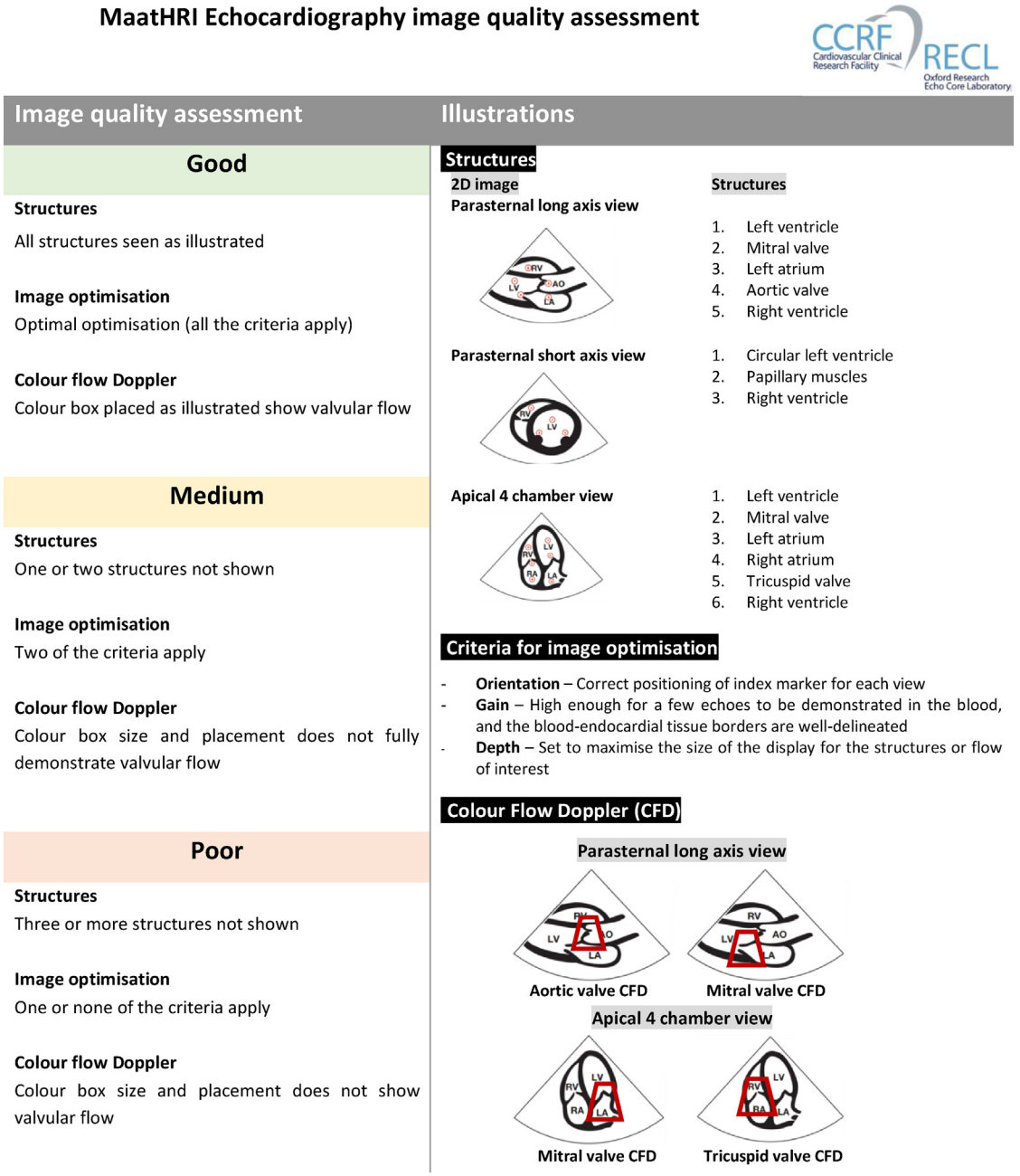

Figure 2 Image quality assessment protocol for MaatHRI focused echocardiography.

dilatation, including three control participants. Pericardial effusion was the most frequent finding and was reported in 89 women (30%), including 16 control participants. Overall, 181 (60%) of the study participants (80% of the cases and 33% of the control subjects) had at least one cardiac abnormality identified using focused echocardiography, and 154 women (51% of the total) had a significant abnormality requiring urgent treatment and follow-up. Twenty-one women in the control group were also found to have significant cardiac abnormalities.

Image Acquisition and Quality

Overall image acquisition using the focused method by the trained obstetricians was satisfactory, with 81% of the scans having the three 2D echocardiographic views listed in the protocol, 17% ($n = 51$) having two of the three views, and <1% of the scans ($n = 2$) having a single view. Only four scans (1.3%) did not include any of the required echocardiographic images listed in the protocol and were therefore excluded from the analysis. The PLAX view was missing in 6.3% of the scans ($n = 19$), while both the PSAX and apical four-chamber views were missing in 5.6% of the scans ($n = 17$).

Image quality assessment was performed for each view. PLAX image quality was assessed as good in 79% ($n = 238$) and was superior to both the PSAX view (75.4%) and the apical four-chamber view (62%), as shown in Figure 5. On average, only 7.6% of the images ($n = 22$) were assessed as poor quality. Image depth and gain optimization were the main reason for lower image quality. The drop in

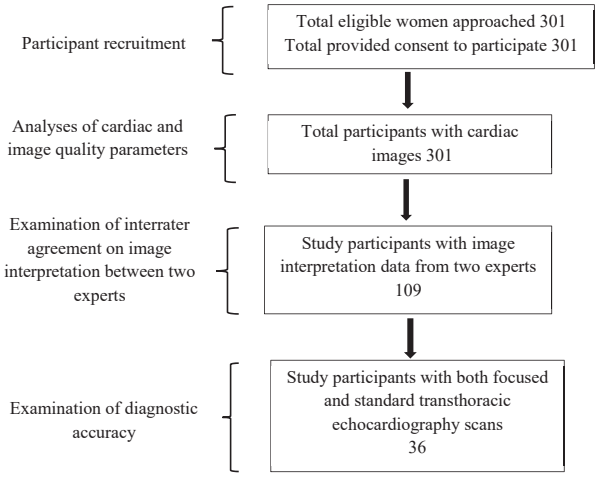

Figure 3 Flow diagram for the study data.

acquisition quality was also related to reported clinical disease severity and advanced pregnancy status.

Agreement on Image Interpretation between the Experts in the United Kingdom and India

Image interpretation agreement between the two experts was examined in 109 scans and is presented for each parameter in Table 4. Overall, there was substantial agreement on valve abnormalities between the two reviewers, with agreement ranging from 95.4% for tricuspid valve regurgitation ($\kappa = 0.852$) and 97.3% for mitral valve regurgitation ($\kappa = 0.921$) to 100% for valvular stenosis, aortic valve regurgitation, and rheumatic heart disease ($\kappa = 1$). There was also good agreement on the parameters for ventricular size and function, the lowest being for LVEF (93.6%, $\kappa = 0.839$). Although the agreement on right ventricular enlargement was 95.4%, the calculated κ coefficient was 0.423. A similarly low κ coefficient was also observed for right atrial enlargement despite agreement between the two experts being 97.3%. Agreement on the presence of pericardial effusion between the experts was 97.3% ($\kappa = 0.932$).

Agreement for the image quality assessment ranged from 87.6% for the apical four-chamber 2D view to 100% for the PLAX view with color flow at the mitral valve. However, the κ coefficients for the quality parameters were low and ranged from 0.275 to 0.513, some with very wide 95% CIs. Overall, it was observed that the quality of the scans was assessed more stringently by the expert from India than the expert in the United Kingdom.

Diagnostic Accuracy between Focused and Standard Scans

There was 78% agreement in the diagnosis of cardiac abnormalities between the focused method and standard transthoracic echocardiography in the 36 participants compared. The discrepancies in 22% of the scans were due primarily to the LVEF parameter and were found to be related to the timing of the scan performed since the patient was admitted (Table 5). Overall, the focused scans were conducted earlier than the standard scans, and the discrepancies were found mainly when the time period between the two scans was wider, with a mean of 2.3 ± 3.5 days, compared with 1.1 ± 1.7 days for those with consistent interpretation.

Table 2 Characteristics of participants included in the study

Characteristic	Patients (n = 172)	Control subjects (n = 129)
Sociodemographics	Mean (min-max)	Mean (min-max)
Age, y*	25.4 (18-42)	23.7 (18-35)
BMI, kg/m^2*	21.1 (13.7-35.6)	21.7 (13.6-32.5)
	Frequency (%)	Number (%)
Religion		
Hindu	97 (56.4)	88 (68.2)
Muslim	60 (34.9)	36 (27.9)
Others	10 (5.8)	5 (3.9)
Missing	5 (2.9)	0
Residence		
Rural	137 (79.7)	112 (86.8)
Urban/semiurban	30 (17.4)	17 (13.2)
Missing	5 (2.9)	0
Living below poverty line		
No	53 (30.8)	28 (21.7)
Yes	105 (61.1)	99 (76.7)
Not known/missing	14 (8.1)	2 (1.6)
Level of education		
Illiterate	33 (19.2)	8 (6.2)
Primary	28 (16.3)	6 (4.7)
Secondary	91 (52.9)	98 (75.9)
Higher	15 (8.7)	17 (13.2)
Missing	5 (2.9)	0
Smoking status		
Never smoked	166 (96.5)	129 (100)
Current smoker	1 (0.6)	0
Missing	5 (2.9)	0
Alcohol consumption		
Never	166 (96.5)	127 (98.5)
Current	1 (0.6)	2 (1.5)
Missing	5 (2.9)	0
Tobacco consumption		
Never/before pregnancy	145 (84.3)	119 (92.3)
Current/gave up during pregnancy	22 (12.8)	10 (7.8)
Missing	5 (2.9)	0
Chewing betel nut		
Never/before pregnancy	90 (52.3)	82 (63.6)
Current/gave up during pregnancy	77 (44.8)	47 (36.4)
Missing	5 (2.9)	0
Obstetric and medical history		
Parity		
Primiparous	93 (54.1)	90 (69.8)

(*Continued*)

Table 2 (*Continued*)

Characteristic	Patients (*n* = 172)	Control subjects (*n* = 129)
Multiparous (one or two previous pregnancies)	56 (32.5)	33 (25.6)
Multiparous (three or more previous pregnancies)	18 (10.5)	6 (4.6)
Missing	5 (2.9)	0
Hypertensive disorders of pregnancy in current pregnancy		
No	109 (63.4)	126 (97.7)
Yes	56 (32.5)	3 (2.3)
Missing	7 (4.1)	0
Received antenatal checkups		
None	15 (8.7)	0
Three or fewer	95 (55.2)	52 (40.3)
More than three	57 (33.1)	77 (59.7)
Missing	5 (2.9)	0
Any preexisting medical problems		
No	129 (75.0)	121 (93.8)
Yes	33 (19.2)	7 (5.4)
Missing	10 (5.8)	1 (0.8)
Clinical characteristics (*n* = 167)	Mean (min-max)	
Systolic blood pressure, mm Hg	124.6 (50-200)	—
Diastolic blood pressure, mm Hg	81.1 (30-120)	—
	Frequency (%)	
NYHA functional class		—
I	13 (7.8)	—
II	37 (22.2)	—
III	19 (11.4)	—
IV	98 (58.6)	—
Not known	0	—
Presenting with tachycardia		—
No	140 (83.9)	—
Yes	27 (16.1)	—
Onset of HF in relation to time period of pregnancy		—
Antenatal period	113 (67.7)	—
Labor and delivery	3 (1.8)	—
Postpartum	51 (30.5)	—
For antenatal onset, median gestational age (range), wk	35 (8-42)	—
For postpartum onset, median number of days after childbirth (range)	1.5 (0.4-150)	—
Woman died		—
No	155 (92.8)	—
Yes	10 (6.0)	—
Not known	2 (1.2)	—
History of cardiac problems		—
None	145 (86.8)	
Rheumatic heart disease	12 (7.2)	—
Other cardiac problems – not specified	5 (3.0)	—
Not known	5 (3.0)	—

BMI, Body mass index; *HF*, heart failure; *NYHA*, New York Heart Association.
Data are expressed as mean (range) or number (percentage) except as indicated. Five women had twin pregnancies (four patients and one control subject).
*Information not available for five patients.

DISCUSSION

Our study showed that FoCUS examination protocols and method can be adapted to use in obstetric settings to accurately identify cardiac abnormalities in pregnant women in low-resource settings. Trained obstetricians in India were able to acquire high-quality cardiac images using portable cardiac ultrasound devices following a simple protocol, which were interpreted remotely by experts following an image interpretation protocol. A variety of cardiac abnormalities were identified in the study population, including valvular abnormalities, rheumatic heart disease, derangements in ventricular size and function, atrial dilatation, and pericardial effusion. Image quality was graded as good in 79% of PLAX, 77% of PSAX, and 64% of apical four-chamber views. There was substantial agreement on the majority of the cardiac parameters between the two experts, but the chance-corrected κ coefficients indicated fair to moderate agreement for the image quality parameters. There was good agreement on diagnosis of abnormalities between the focused method and standard transthoracic echocardiography (78% agreement), compared in 36 participants.

Our findings are supported by other studies that have demonstrated that the diagnostic utility of portable echocardiography is comparable with that of standard echocardiography, and portable machines are useful in low-resource settings.[6,26] Diagnostic agreement between standard scans and portable echocardiography interpreted by experts was found to be 88% in a study from the United States,[27] which is higher than the 78% found in our study. However, the lower agreement in our study was likely due to the time gap between the two scans and not related to the quality of the images. Another study conducted in a pediatric population in

Table 3 Echocardiographic abnormalities identified in the study participants using the FoCUS method

	Frequency (%)
Valve abnormalities	
Aortic valve stenosis (n = 281)	1 (0.4)
Nonsignificant	—
Significant	1 (0.4)
Aortic valve regurgitation (n = 271)	15 (5.5)
Nonsignificant	12 (4.4)
Significant	3 (1.1)
Mitral valve stenosis (n = 269)	17 (6.3)
Nonsignificant	—
Significant	17 (6.3)
Mitral valve regurgitation (n = 290)	64 (22.1)
Nonsignificant	39 (13.4)
Significant	25 (8.6)
Tricuspid valve stenosis* present (n = 275)	2 (0.7)
Tricuspid valve regurgitation (n = 263)	59 (22.4)
Nonsignificant	47 (17.9)
Significant	12 (4.5)
Rheumatic valve disease (n = 301)†	20 (6.6)
Aortic valve involvement	3 (1)
Mitral valve involvement	20 (6.6)
Tricuspid valve involvement	4 (1.3)
Ventricular size and function	
LV enlargement (n = 297)	14 (4.7)
LVEDD 5.4-5.7 cm	13 (4.4)
LVEDD 5.8-6.1 cm	1 (0.3)
LVEDD > 6.1 cm	0 (0)
LVEF (n = 296)	
>70%	4 (1.4)
55%-69%	227 (76.7)
45%-54%	25 (8.4)
30%-44%	26 (8.8)
<30%	14 (4.7)
LV regional wall motion abnormalities present (n = 297)	28 (9.4)
RV enlargement/RV basal diameter > 4.2 cm (n = 285)	19 (6.7)
RV regional wall motion abnormalities present (n = 283)	6 (2.1)
Atrial size	
Left atrial enlargement (n = 292)	57 (19.5)
Right atrial enlargement (n = 282)	28 (9.9)
Other parameters	
Pericardial effusion (n = 297)	89 (30)
Thrombus (n = 293)	4 (1.4)

LV, Left ventricular; *LVEDD*, left ventricular end-diastolic diameter; *RV*, right ventricular.
n denotes the number of scans in which the parameter could be assessed among a total of 301 scans.
*Categorized as present or absent.
†The subgroups of valve involvement do not add up to 20, as more than one valve was involved in some participants.

the United States found good agreement on LVEF ($\kappa = 0.81$), left and right ventricular structure and function ($\kappa = 0.75$ for left ventricular structure to 1.00 for others), and pericardial effusion ($\kappa = 0.66$) between focused echocardiography (using Philips Lumify) with visual and/or semiquantitative analysis and standard echocardiography.[28]

Although we observed a higher degree of precision among the obstetricians in acquiring PLAX and PSAX views, the apical four-chamber view was relatively difficult, particularly in women with advanced pregnancy and/or increased severity of cardiac problems. Obtaining a perfect acoustic window for the apical four-chamber view is often difficult for nonexperts, as this is significantly influenced by the patient's condition and pregnancy status. Increasing the number of views and regular practice by obstetricians in acquiring the images can further improve diagnostic accuracy. A study showed that technical proficiency in acquiring images by nonexperts improved at a rate of 0.79 points (95% CI, 0.53-1.04 points) on an overall assessment index (ranging from 0 to 3) per 10 scans completed.[29] A systematic review revealed that nonexperts with different levels of skills require different lengths of training and hands-on practice, but proficiency was generally seen to be achieved after 30 to 50 scans.[30]

Previous studies showed that diagnostic accuracy is higher and more precise when the images are interpreted by experts compared with interpretation by nonexperts.[31] The level of agreement on all cardiac parameters between two experts independently reading the images remotely was high, ranging from 93.6% to 100%. This demonstrates the reliability of the semiquantitative protocol used for image interpretation. Cohen's κ statistic measures the degree of agreement relative to what would be expected by chance alone. This is an additional statistical measure that indicated the likelihood of the calculated percentage agreement between the experts being due to chance alone. The κ coefficient is 0 when the proportion of

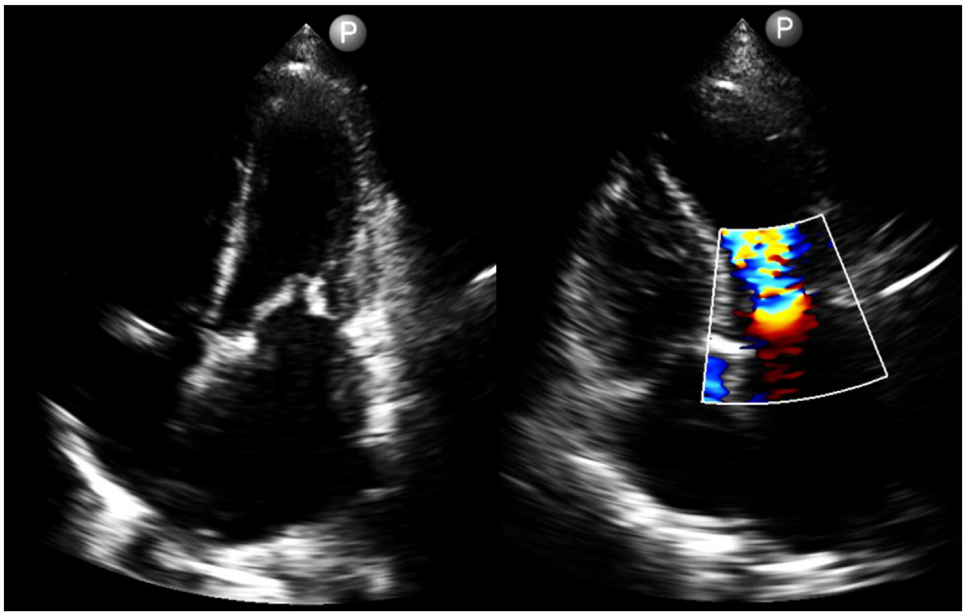

Figure 4 A patient with heart failure with rheumatic heart disease and significant mitral stenosis.

agreement is equal to what would have been expected by chance and 1 when there is perfect agreement not attributed to chance. Cohen's κ statistics in the range of 0.81 to 1.00 denote near perfect agreement, 0.61 to 0.80 substantial agreement, 0.41 to 0.60 moderate agreement, and 0.21 to 0.40 fair agreement. On the basis of this, the chance-corrected agreement between the experts could be graded as substantial for all parameters except two, right ventricular and right atrial enlargement. Despite high percentage agreement, the low κ statistics observed for right ventricular ($\kappa = 0.423$) and right atrial ($\kappa = 0.386$) enlargement and for six image quality parameters can be explained by the first κ paradox.[32,33] The first κ paradox, in which κ values are low despite high percentage agreement, arises when the expected or hypothetical agreement between the rates is high. In this case, even if the observed agreement is high, the calculated κ will be low. The expected agreement is determined by the distribution of the data in the study population for each indicator.

Image quality assessment could be made more objective by using a quantitative image acquisition assessment tool, such as the one developed by Gaudet *et al.*,[34] to assign a score to structures observed in each view that were added to generate an overall quality score. Furthermore, evolving technology of the portable machines would allow automated calculation of ventricular size and function using artificial intelligence to enable more objective and accurate assessments.[35]

Strengths and Limitations

To our knowledge, this is the first study that adapted and tested the FoCUS method in an obstetric setting. We used a robust and standardized methodology to develop and validate the image acquisition and image interpretation protocols in a sample of 301 pregnant and postpartum women from 10 hospitals across three states in India. Although this was a multicenter study, the generalizability of the findings across all hospital settings in India and other LMICs is limited because of varying levels of basic training of obstetricians in conducting ultrasonography. We found that obstetricians who had experience of conducting obstetric scans required less training and were able to obtain better quality images, but we did not undertake a formal assessment of the association between image quality and the level of prior ultrasonography training. Obstetricians were not involved in interpreting the images, and we did not assess the accuracy of an interpretation performed by the obstetrician who performed the imaging. Therefore, the findings of this study should not be misinterpreted as suggesting that obstetricians made accurate interpretations of the echocardiograms. As recommended for FoCUS examinations,[6] we were able to compare a subset of the images with comprehensive echocardiography, but this was performed at a single hospital and on 36 participants, so the results may not be generalizable to other settings. Furthermore, not all 301 women underwent comprehensive echocardiography, so it is not known how many

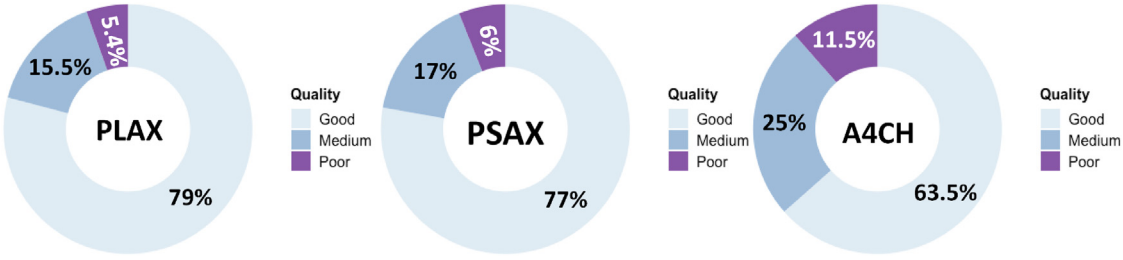

Figure 5 Image quality assessment for the PLAX, PSAX, and apical four-chamber (A4CH) views.

Table 4 Cardiac parameters evaluated and the agreement between the experts

Parameter	*n*	Agreement (%)	κ	95% CI	*P*
Valve abnormalities					
Aortic valve stenosis	106	100	1	1.00 to 1.00	<.001
Aortic valve regurgitation	106	100	1	1.00 to 1.00	<.001
Mitral valve stenosis	109	100	1	1.00 to 1.00	<.001
Mitral valve regurgitation	109	97.25	0.921	0.884 to 0.955	<.001
Tricuspid valve stenosis	109	100	NA	—	—
Tricuspid valve regurgitation	108	95.37	0.852	0.829 to 0.900	<.001
Rheumatic valve disease	109	100	1	1.00 to 1.00	<.001
Ventricular size and function					
Left ventricular enlargement	109	97.25	0.809	0.600 to 1.000	<.001
LVEF	109	93.58	0.839	0.717 to 0.890	<.001
Left ventricular regional wall motion abnormalities	109	96.33	0.648	0.328 to 0.968	<.001
Right ventricular enlargement	109	95.41	0.423	0.012 to 0.834	<.001
Right ventricular regional wall motion abnormalities	109	99.08	NA	—	—
Atrial size					
Left atrial enlargement	109	94.50	0.638	0.373 to 0.903	<.001
Right atrial enlargement	109	97.25	0.386	−0.163 to 0.936	<.001
Other parameters					
Pericardial effusion	109	97.25	0.932	0.856 to 1.000	<.001
Thrombus	109	100	1	1.00 to 1.00	<.001
Tachycardia	109	96.33	0.798	0.606 to 0.990	<.001
Image quality for each view					
PLAX 2D	106	96.23	0.480	0.045 to 0.916	<.001
PLAX color flow at mitral valve	106	100	NA	—	—
PLAX color flow at aortic valve	106	97.17	0.388	−0.013 to 0.495	<.001
PSAX 2D	109	94.50	0.513	0.460 to 0.732	<.001
Apical four-chamber 2D	105	87.62	0.275	0.196 to 0.351	<.001
Apical four-chamber color flow at mitral valve	107	90.65	0.409	0.225 to 0.567	<.001
Apical four-chamber color flow at tricuspid valve	106	92.45	0.317	0.000 to 0.604	<.001

n, Total number of scans analyzed for each parameter; *NA*, κ could not be calculated for parameters with two categories of rating for which all individuals had almost exactly the same rating by both experts.

pathologic findings were missed. The FoCUS method has a limited capacity to examine cardiovascular problems because of the reduced number of views, and we were unable to examine the inferior vena cava, because of the reasons mentioned earlier. However, the standard views that we used are known to be adequate in diagnosing acute and overt cardiac problems[6,10] and were found to accurately identify cardiac abnormalities prevalent in our study population.

An inherent limitation of the FoCUS approach, which might have affected our study, is higher probability of a foreshortened left ventricle in the four-chamber view, leading to an underestimation of ventricular size and/or an overestimation of the left ventricular function.[10] FoCUS acknowledges the variability in image quality on the basis of operator experience, and therefore subtle cardiac abnormalities could be difficult to detect. However, as our objective was not to estimate the exact size of the ventricles but to identify the presence or absence of ventricular enlargements, the bias in the results is likely to be low. Similarly, we acknowledge that it is not possible to measure LVEF accurately from the limited number of views, as visualization of several segments is ideally required to accurately calculate LVEF. We also acknowledge that defining severity of stenosis from just qualitative assessment of valve morphology and motion and color Doppler is rudimentary, and in cases in which intracardiac flow is low, severity could be misjudged. We acknowledge that the study was not designed to assess whether patient outcomes were altered

Table 5 Comparison of cardiac abnormalities identified using the focused method and comprehensive standard scan

Participant	Number of days between focused and comprehensive scans*	Agreement between the focused and standard scan reports		
		LVEF concordant/discordant	Valvular/other abnormalities concordant/discordant	Details of discordant pathologies
1	4	Discordant	Concordant	Focused scan: reduced LVEF (30%-40%) Standard scan: normal
2	0	Concordant	Concordant	
3	0	Concordant	Concordant	
4	0	Concordant	Concordant	
5	0	Concordant	Concordant	
6	2	Concordant	Concordant	
7	−2	Concordant	Concordant	
8	5	Discordant	Discordant	Focused scan: normal LVEF with PE Standard scan: dilated left ventricle with decreased LVEF
9	1	Concordant	Discordant	Focused scan: mild MR, PE, LA enlargement Standard scan: normal with signs of constrictive pericarditis
10	−2	Concordant	Concordant	
11	0	Concordant	Concordant	
12	0	Concordant	Concordant	
13	4	Concordant	Concordant	
14	2	Concordant	Concordant	
15	0	Concordant	Discordant	Focused scan: mild TR, LVEF 45%-54% Standard scan: low LVEF, no valvular abnormalities
16	−1	Discordant	Concordant	Focused scan: normal Standard scan: low LVEF (45%) with tachycardia
17	0	Concordant	Concordant	
18	0	Concordant	Concordant	
19	0	Concordant	Discordant	Focused scan: mild TR, PE, enlarged atria Standard scan: moderate TR, high output, borderline LV dilatation
20	0	Concordant	Concordant	
21	2	Concordant	Concordant	
22	0	Concordant	Concordant	
23	1	Concordant	Concordant	
24	0	Concordant	Concordant	
25	1	Discordant	Discordant	Focused scan: mild MR, mild TR, LVEF 30%-44% Standard scan: normal
26	2	Concordant	Concordant	
27	4	Concordant	Concordant	

(*Continued*)

Table 5 (*Continued*)

Participant	Number of days between focused and comprehensive scans*	Agreement between the focused and standard scan reports		
		LVEF concordant/discordant	Valvular/other abnormalities concordant/discordant	Details of discordant pathologies
28	5	Concordant	Concordant	
29	1	Concordant	Concordant	
30	1	Discordant	Discordant	Focused scan: moderate MR, mild TR, dilated left ventricle, LVEF < 30%, small PE Standard scan: normal
31	1	Concordant	Concordant	
32	4	Concordant	Concordant	
33	10	Discordant	Concordant	Focused scan: LVEF 30%-40% Standard scan: normal
34	2	Concordant	Concordant	
35	2	Concordant	Concordant	
36	1	Concordant	Concordant	

LA, Left atrial; *LV*, left ventricular; *MR*, mitral regurgitation; *PE*, pericardial effusion; *TR*, tricuspid regurgitation.
*Number of days is positive when focus echocardiography was performed before comprehensive echocardiography and negative when comprehensive echocardiography was performed before focused echocardiography.

by the use of the FOCUS examination. For example, we did not assess if the performance of the FOCUS examination led to a change in management or a new diagnosis that would not have been made without the imaging. However, we plan to do so in a subsequent study.

Another inherent limitation of the portable devices is the lack of a comprehensive measurement software that can analyze DICOM images,[28] but we found that both freely available basic DICOM image analysis software as well as advanced image analysis software such as OsiriX MD can be reliably used for qualitative interpretation of the images. This makes our tested method low cost and therefore usable in low-resource settings.

CONCLUSION

The focused echocardiographic method for obstetricians that we developed and tested enabled us to conduct cardiac imaging using a portable device in all participants recruited in our study within 12 to 24 hours of hospital admission, even in settings where standard echocardiography was not readily available. Importantly, 51% of the study participants were found to have significant cardiac abnormalities requiring urgent treatment and follow-up, including 21 women from the control group who were not suspected of having heart disease. Thus, our tested method could be lifesaving in situations in which immediate intervention is required, such as emergency pericardiocentesis in pregnant or postpartum women with severe tamponade. In low-resource settings where there is a shortage of cardiologists or significant travel is required to reach a facility with a cardiologist, focused echocardiography could be used in obstetric settings to prioritize pregnant women who need such referrals. It can be used for screening cardiac problems during antenatal checkups in pregnant women who present with breathlessness, fatigue, palpitation, and other symptoms or with known risk factors for cardiovascular diseases. Use in LMICs is also made possible by the growing availability of low-cost portable machines approved for clinical use.[7,9] However, further studies are needed to evaluate the effectiveness of screening, and processes should be developed for accreditation of obstetricians for proficiency in image acquisition and identification of legal and ethical implications for using the method in antenatal screening.

SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.echo.2022.07.014.

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